

### **REMARKS**

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

#### **Personal Interview**

Applicant and the undersigned wish to thank Mr. Paul Prebilic, the patent examiner in charge of this application, for the courteous and productive interview conducted on 5 June 2007 with the undersigned and the Applicant, Dr. Timothy Murphy. Because Applicant was not relieved of the duty under 37 C.F.R. § 1.133(b) of providing a summary of the arguments presented during that interview, Applicant provides the following comments.

The interview began with Dr. Murphy briefly discussing the subject matter described and claimed in this application, to wit, methods useful for treating morbid obesity in patients. Dr. Murphy continued by explaining that Dr. Murphy had twice applied to the National Institutes of Health, specifically the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Biomedical Imaging and Bioengineering, for grants to further study and develop the subject matter described and claimed in this application. Applicant submits herewith copies of those NIH grant applications. During the interview, Dr. Murphy presented to Mr. Prebilic copies of the NIH's responses to those grant requests, copies of which are also appended hereto.

The two NIH grant responses bear directly on the positions stated in the Office Action because they are objective evidence of non-obviousness of the claimed subject matters. During the interview, the undersigned emphasized to Mr. Prebilic that the NIH grant responses are evidence of non-obviousness different in kind from the sorts of 'evidence' often submitted in patent applications, because the NIH grant responses: (1) were prepared by a U.S. government agency not concerned with patentability, but instead with safety and public health; (2) were signed by a panel of experts in the medical fields with which the technology deals, which experts have no connection with Dr. Murphy or this patent application; (3) were not solicited in order to respond to the Office Action and its rejections; and (4) essentially state that the claimed methods,

as embodied in the experimental protocols described in the NIH grant applications, were not only noted to be “highly innovative”, but were felt to be so unconventional that they were considered by several reviewers to be both unsafe and unethical.

Mr. Prebilic indicated that he would fully consider the NIH grant applications and responses thereto upon formal submission in response to the Office Action, in accordance with the guidelines for such considerations in the M.P.E.P.

### **Rejection under 35 U.S.C. § 103(a)**

In the Office Action, beginning at page 2, Claims 1, 3-6, 8-10, and 12-14 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over *Flesler* in view of *Ruiz*. Claim 11 was again rejected under section 103(a) as reciting subject matter that allegedly is obvious, and therefore allegedly is unpatentable, over *Flesler* and *Ruiz* in view of *Yurek*. Applicant respectfully requests reconsideration of these rejections.

Applicant previously summarized some aspects of the technologies described and claimed in this application, in the Amendment filed 22 December 2006; Applicant will not burden the record with a redundant summary, and therefore merely incorporates the prior discussions by reference.

Claim 1 relates to a method of treating morbid obesity in a patient comprising reducing gastric blood flow, duodenal blood flow, mesenteric blood flow, jejunal blood flow, ileal blood flow, or combinations thereof, in the patient, including placing a blood flow reducing device inside an artery that carries blood to the small intestine.

The prior art, including *Flesler* and *Ruiz*, fails to disclose or fairly suggest methods as recited in the pending claims.

*Flesler* describes systems and methods allegedly useful for treating obesity in a patient. *Flesler* uses intermittent electrical stimulation on the exterior of “or in the vicinity of” (para. [0113]) the superior mesenteric artery 110, to intermittently narrow the mesenteric arteries, only after meals. Because *Flesler* applies electrical stimulation to the muscle cells of the artery,

whatever constriction *Flesler* may be able to achieve, can't be controlled. That is, the amount of narrowing occurring in the arteries would not be apparent to any observer, may be more than is safe (leading to clotting or acute blockage of the arteries with a high risk of bowel infarction/death and patient death), or less than is necessary to achieve the goal of incomplete absorption or hindered digestion. That is, the amount of narrowing of the artery by electrical stimulation is not consistent and reproducible. *Flesler* acknowledges and prefers that any reduction in the blood flow through the artery is discontinuous, variable, and not permanent: "The constriction produced by apparatus 118 preferably transiently and controllably reduces the blood flow to small intestine 120. . .". Para. [0113]. *Flesler* also emphasizes that his methods are to be used only with meals, and are not permanent solutions.

*Flesler* fails to identically disclose or fairly suggest the subject matters recited in the pending claims, and *Ruiz* fails to make up for the deficiencies of *Flesler* with respect to the subject matters of the claims. *Ruiz* describes a blood flow restriction stent 10 with an adjustable internal diameter, which is installed in the pulmonary artery PA of a patient.

In the December 22<sup>nd</sup> Amendment, Applicant argued that one of ordinary skill in the art would not be motivated to modify the methods of *Flesler* with the use of *Ruiz*'s device, and therefore that the claimed methods are patentable; Applicant reiterates those arguments and incorporates them by reference herein.

The NIH grant responses are strong evidence of non-obviousness of the claimed methods. As discussed above, the NIH grant responses include discussions by true experts in the field of Dr. Murphy's methods and the effects in patients that the methods would have. Applicant points out that these impartial experts repeatedly commented in the NIH grant responses that Dr. Murphy's methods are 'novel' and 'innovative'. More importantly with respect to the non-obviousness of the claimed methods, both of the NIH grant responses caution against the practice of the methods which, in the experts' opinions, would cause severe pain and 'food fear' in the patients. Indeed, several of the comments in the NIH grant responses go so far as to suggest that performing these methods may be medically 'unethical'. Thus, in essence, the panels of experts assembled by the NIH to assess Dr. Murphy's grant applications on the claimed methods are

strongly of the opinion that a person of ordinary skill in this art should not perform the methods that are currently claimed, based on their extensive and deep knowledge and experiences in exactly the field of Dr. Murphy's endeavors.

Therefore, the NIH grant responses indicate that the medical community concerned with Dr. Murphy's invention, including those of ordinary skill in the art to which these inventions pertain, does not at all find Applicant's claimed methods to be obvious and, strongly to the contrary, are of the opinion that practitioners in these fields should not perform them. Thus, the evidence in this record strongly shows that a person of ordinary skill in the art, at the time of Applicant's invention, would not be motivated to perform the methods recited in the pending claims and, indeed, would likely find them implausible, contrary to their medical knowledge, and abhorrent.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 1, 3-6, and 8-14, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

### **Rejections under 35 U.S.C. § 102 or § 103**

In the Office Action, beginning at page 4, Claims 23-25 were rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by *Flesler*, or, in the alternative, are unpatentable under 35 U.S.C. § 103 over *Flesler* in view of *Ruiz*. Applicant respectfully requests reconsideration of these alternative rejections.

Claim 23 relates to a method of treating morbid obesity in a patient comprising permanently reducing blood flow in particular vessels in the patient. Claim 24 relates to a method of treating morbid obesity in a patient comprising reducing blood flow in particular vessels a fixed, invariable amount in the patient. Claim 25 relates to a method of treating morbid obesity in a patient comprising continuously reducing blood flow in particular vessels in the patient for a time effective to reduce the patient's weight.

Applicant has addressed above the hypothetical combination of *Flesler* and *Ruiz*, and Claims 23-25 are patentable for at least the same reasons as Claim 1 above.

The Office Action alleges that several of the terms used in Claims 23-25 are identically met by *Flesler*, stating:

The reduction is considered to be permanent, fixed, invariable, and continuous to the extent required because these terms are terms of relative degree. The *Flesler* can and is used for permanent, fixed, invariable, and continuous way at least for a period of time.

Applicant strongly disagrees.

There is nothing relative about any of the accused terms. Applicant has used the particular terms in the claims in their normal English usage, and the Office Action's cavalier announcement that they are "terms of relative degree" is plainly wrong. It is truly incomprehensible how any of these terms are dependent on, and therefore relative to, any other parameter; certainly, the Office Action's inability to identify the other things upon which these terms could possibly vary is a plain indication that, in fact, there are no such other variables. M.P.E.P. § 2173.05(b) discussed at great length what are the sorts of terms that are "terms of relative degree", and none of the terms used in the pending claims are of that ilk. M.P.E.P. § 2111.01 instructs the patent examining corps that "THE WORDS OF A CLAIM MUST BE GIVEN THEIR 'PLAIN MEANING' UNLESS SUCH MEANING IS INCONSISTENT WITH THE SPECIFICATION" (emphasis in original); the use of the claim terms is completely consistent with the use in the specification and are their 'plain meanings'. The Office Action's attempted lexicography is clearly an error, and the prior art plainly fails to disclose, describe, or fairly suggest methods for treating morbid obesity which involve permanent, fixed, invariable, and/or continuous reduction in the blood flow through blood vessels as recited in the pending claims.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 23-25 are not anticipated by *Flesler* and are not obvious in view of *Flesler* in view of *Ruiz*, are therefore not unpatentable under 35 U.S.C. §§ 102, 103, and therefore respectfully

requests withdrawal of the rejections thereof.

### **Conclusion**

Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of this patent application is therefore respectfully solicited.

If Mr. Prebilic believes that a telephone conference with the undersigned would expedite passage of this patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-2821.

Respectfully submitted,

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